



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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WARNING LETTER
NWE-08-07W

VIA FEDERAL EXPRESS

December 21, 2006

George C. Palmer and John Palmer, Co-Owners
Palmer Farms
1 East Clarks Falls Road
North Stonington, CT 06359

Dear Messers Palmer:

An inspection of your cattle operation located at 2 Clarks Falls Road, North Stonington, CT conducted by representatives of the U.S. Food and Drug Administration (FDA) on October 11, and 19, 2006 confirmed that you offered an animal for sale for slaughter as food that was adulterated under sections 402(a)(2)(C)(ii) [21 U.S.C. 342(a)(2)(C)(ii) and 402(a)(4) [21 U.S.C. § 342 (a)(4)] of the Federal Food Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused the new animal drug penicillin G procaine to be unsafe under Section 512 [21 U.S.C. § 360b] of the Act and adulterated within the meaning of section 501(a)(5) [21 U.S.C. § 351(a)(5)]. You can find the Act and its associated regulations on the Internet through links on the FDA's web page at www.fda.gov.

On or about June 19, 2006, you consigned a dairy cow from your farm, identified with farm tag 1625 to be sold for human food. You paid [REDACTED] to transport this cow to [REDACTED] where it was assigned back tag 16CR1443. The cow was sold the same day to [REDACTED] where it was slaughtered for food on June 20, 2006. The United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from that animal on June 20, 2006, identified the presence of 0.59 parts per million (ppm) of penicillin in the kidney tissue of this cow. A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle as codified in the Title 21, Code of Federal Regulations, section 556.510 (21

C.F.R. 556.510). The presence of this drug in edible tissues from this animal above the established tolerance causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) [21 U.S.C. § 342(a)(2)(C)(ii)] of the Act.

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system to ensure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, you failed to maintain treatment records, and you lack an adequate inventory system for determining the quantities of drugs used to medicate your animals. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) [21 U.S.C. § 342(a)(4)] of the Act.

In addition, you adulterated penicillin G procaine within the meaning of section 501(a)(5) [21 U.S.C. § 351(a)(5)] of the Act when you failed to use the drug in conformance with its approved labeling. "Extralabel use", i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship. The extralabel use of approved veterinary or human drugs must comply with sections 512(a)(4) and 512(a)(5) of the Act and 21 C.F.R. Part 530. Our investigation found that your extralabel use of penicillin G procaine failed to comply with these requirements.

For example, you administered penicillin G procaine without following the dosage level, route of administration, and withdrawal period for cattle set forth in the approved labeling and you did so without the supervision of a licensed veterinarian, in violation of 21 C.F.R. 530.11(a). You administered [REDACTED] of penicillin G procaine in one (1) injection site on the dairy cow with farm tag 1625. You have no treatment records indicating when the drug was administered to the cow. You used a dose higher than the label dose; administered [REDACTED] and you did not use an extended withdrawal time prescribed by a veterinarian. Furthermore, your extralabel use resulted in an illegal drug residue, in violation of 21 C.F.R. 530.11(d). Because your extralabel use of this drug was not in compliance with 21 C.F.R. Part 530, the drug was unsafe under section 512(a) [21 U.S.C. § 360b(a)] of the Act and your use caused it to be adulterated within the meaning of section 501(a)(5) [21 U.S.C. § 351(a)(5)] of the Act.

Our investigators also observed a number of expired new animal drugs in your drug storage area. Using an expired new animal drug to treat your animals would result in the drug being unsafe within the meaning of section 512(a) of the Act [21 U.S.C. § 360b(a)] because such use would be in a manner other than in accordance with the drug's approved application. An unsafe new animal drug is adulterated within the meaning of section 501(a)(5) [21 U.S.C. § 351(a)(5)]. As stated above, the extralabel use of approved animal and human drugs is only permitted if the use is on or by the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and such use complies with sections 512(a)(4) and 512(a)(5) of the

Act [21 U.S.C. §§ 360b(a)(4) and (a)(5)] and the extralabel use regulations set forth in 21 C.F.R. Part 530.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction,

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within 15 working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violation and prevent its recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Anthony P. Costello, Compliance Officer, 1 Montvale Avenue, Stoneham, MA 02180. If you have any questions you can contact Mr. Costello at 781 596-7716.

Sincerely,



Anthony P. Costello
District Director
New England District Office

cc:

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